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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Barbara Enenkel et al) Art Unit: 1632
U.S. Appln. No. : 10/724,266) Examiner: To be assigned
Confirmation No. : 1242
U.S. Filing Date : November 26, 2003
Title of Invention : EXPRESSION VECTOR, METHODS FOR THE PRODUCTION OF
HETEROLOGOUS GENE PRODUCTS AND FOR THE SELECTION
OF RECOMBINANT CELLS PRODUCING HIGH LEVELS OF SUCH
PRODUCTS
Attny. Docket No. : 1/1412

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

June 21, 2004

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Susan K. Pocchiari

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	5
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Complete if Known

Application Number	10/724,266
Filing Date	November 26, 2003
First Named Inventor	Barbara Enenkel et al
Art Unit	1632
Examiner Name	To be assigned
Attorney Docket Number	1/1412

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 97/15664	05/01/1997	Dr. Karl Thomae GmbH		
		WO 98/32869	07/30/1998	Neurosearch		
		WO 02/094325 A2	11/28/2002	Boehringer Ingelheim International GmbH		
		WO 01/04306 A1	01/18/2001	Genentech, Inc.		
		WO 99/53046	10/21/1999	Chiron Corporation		

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Sheet

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U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
		US-			
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		DE 19539493 A1	04/30/1997	Dr. Karl Thomae GmbH		

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		CHARLES G. BAILEY ET AL; High-Throughput Clonal Selection of Recombinant CHO Cells Using a Dominant Selectable and Amplifiable Metallothionein-GFP Fusion Protein; Biotechnology and Biomolecular 12/20/2002 Vol. 7 page 670-676; Wiley Periodicals, Inc.	
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		YOSHIKAZU SUGIMOTO ET AL; Efficient Expression of Drug-selectable Genes in Retroviral Vectors Under Control of an Internal Ribosome Entry Site; Biotechnology (July 1994) Vol. 12 pages 694-698; National Cancer Institute	
		N. RAMESH ET AL; High-titer bicistronic retroviral vectors employing foot-and-mouth disease virus internal ribosome entry site; Nucleic Acids Research (1996) Vol. 24 No. 14 pages 2697-2700; Oxford University Press	

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		MICHAEL PRIMIG 1 ET AL; A novel GFPneo vector designed for the isolation and analysis of enhancer elements in transfected mammalian cells; International Journal of Genes and Genomes (1998) Vol 215 pages 181-189; Elsevier Science B.V.	
		JERRY PELLETIER ET AL; Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA; Nature (July 1988) Vol. 334 pages 320-325; Department of Biochemistry McGill Cancer Center, McGill University Montreal Canada	
		RICHARD A. MORGAN ET AL; Retroviral vectors containing putative internal ribosome entry sites: development of a polycistronic gene transfer system and applications to human gene therapy; Nucleic Acids Research (February 10, 1992) Vol. 20 No. 6 pages 1293-1299; Molecular Hematology Branch, Bethesda MD.	
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		ALEXANDER N. GUBIN ET AL; Long-Term, Stable Expression of Green Fluorescent Protein in Mammalian Cells; Biochemical and Biophysical Research Communications (1997) Vol. 236 pages 347-350; Academic Press	
		MARTIN CHALFIE ET AL; Green Fluorescent Protein as a Marker for Gene Expression; Science (February 11, 1994) Vol. 263 pages 802-805; Department of Biological Sciences, Columbia University New York, NY	

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First Named Inventor

Barbara Enenkel

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		MONIQUE V. DAVIES ET AL; The Sequence Context of the Initiation Codon in the Encephalomyocarditis Virus Leader Modulates Efficiency of Internal Translation Initiation; Journal of Virology (April 1992) Vol. 66 No. 4 pages 1924-1932; American Society for Microbiology	
		MOHAMMED A. ADAM ET AL; Internal Initiation of Translation in Retroviral Vectors Carrying Picornavirus 5' Nontranslated Regions; Journal of Virology (September 1991) Vol. 65 No. 9 pages 4985-4990; American Society for Microbiology	
		RANDAL J. KAUFMAN ET AL; Amplification and Expression of Sequences Cotransfected with a Modular Dihydrofolate Reductase Complementary DNA Gene; J. Mol. Biol. (1982) Vol. 159 pages 601-621; Center for Cancer Research and Department of Biology, Cambridge Mass.	
		International Search Report Reference No. PCT/EP 03/13225	

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